

Claims 73 has been amended to specify "ethyl cellulose" to simplify the claim. Support for this amendment can be found at page 23, lines 16-17. Claims 79, 80, and 81 have been amended to correct dependency and antecedent basis. New claim 100 has been presented as an alternative to the claim language in claim 47. The same support for amended claim 47 applies to new claim 100, with further support as indicated below:

"a nail afflicted with a fungal infection"	Page 7, lines 16-17.
"said film delivering to said nail water, antifungal agent and keratolytic agent from said composition"	Page 19, lines 9-13.
"for a prolonged period of time"	Page 18, line 14.

Dependent claims 50, 51, 54, 55, 58, 59, 61, 62, 64, 65, 67, 68, 75, 84, 85, 86, and 94, have been canceled, without prejudice or disclaimer to simplify the issues. To the extent broader claims are still pending, they encompass the subject matter of the canceled dependent claims. Therefore, claims 47-49, 52, 53, 56-57, 60, 63, 66, 69-74, 76-83, 87-93, and 95-100 are pending. No new matter has been added by these amendments. Reconsideration of the above identified application, in view of the above amendments and the following remarks, is respectfully requested.

Cancellation of Scheduled Interview and Indication of Allowability

Applicants thank the Examiner and the Primary Examiner for their courteous willingness to prepare for and participate in a telephone interview scheduled for August 27, 2003. At the last minute, the Supervisory Primary Examiner (whose participation had originally been requested) became available. He kindly considered the Applicants' proposed amendments (claims 47, 96 and 98) and summary argument, and advised applicants that the interview would not be necessary and that if the proposed amendment was submitted, the application would be allowed. The Supervisory Primary Examiner specified that he was quite familiar with the differences between skin and nail and that no evidentiary references would be necessary.

Serial No. 09/534,960

Response to Office Action dated April 8, 2003

{M:\3940\0k188\00049991.DOC 10/08/03 10:00:00}

Docket No. 3940/OK188

12

①

Reiteration of Applicants' Position in Traversing the Rejection

In the Office Action dated April 8, 2003, the Examiner maintained the rejection of claims 47-93, 95-97, and 98-99 under 103(a) as unpatentable over Bohn (U.S. Patent No. 5,264,206) in view of Friedman (U.S. Patent No. 5,160,737).

Applicants have amended the claims only to emphasize and/or to clarify the claimed subject matter. No amendment is made to distinguish over the prior art. Nonetheless, Applicants outline the fact that Friedman is not directed to the treatment of nails and does not disclose a keratolytic agent. Further, applicants submit that treatment of skin (as disclosed in Friedman) is very different from nails in structure, composition and behavior.

Fungal infections of nails are tenacious and difficult to treat. While it may be considered as facilitating nail permeability, water is also recognized as promoting fungal growth (Response 12/17/02, Exhibits B and C respectively, especially MSN page 1, lines 11-30 and Medline page 2, lines 3-7). In the present claims, water is not merely contacted with the nail for a short period of time (until the varnish dries). Instead, it is trapped in a sustained release formulation (absent in Bohn) and further retained therein by a humectant which would further delay its evaporation and prolong contact of water with the nail for a period of time substantially longer than any period of time that untrapped water would be present in contact with the nail in the Bohn formulation. It is therefore counterintuitive to include large amounts of humectant and water in a sustained release nail lacquer formulation, and Friedman (inapplicable to nail lacquers) cannot be used to remedy the deficiency in Bohn.

Applicants submit that it is inappropriate to (i) assume that Friedman applies to nails and (ii) apply teachings about how to treat skin to treatment of nails. Friedman cannot be combined willy nilly with Bohn. Therefore, it would not be obvious to one skilled in the art to use the sustained release film in Friedman in the nail varnish taught by Bohn.

Therefore, in view of the above remarks, it is respectfully requested that the application be reconsidered and that all pending claims be allowed and the case passed to issue.

D

If there are any other issues remaining which the Examiner believes could be resolved through either a Supplemental Response or an Examiner's Amendment, the Examiner is respectfully requested to contact the undersigned at the telephone number indicated below.

Respectfully submitted,

Sandra Lee

Sandra S. Lee
Reg. No. 51,932
Attorney for Applicants

DARBY & DARBY, P.C.
Post Office Box 5257
New York, NY 10150-5257
Phone (212) 527-7700

Serial No. 09/534,960
Response to Office Action dated April 8, 2003
{M:\3940\OK188\00049991.DOC }

Docket No. 3940/OK188

14

D

CERTIFICATE OF FACSIMILE TRANSMISSION

I hereby certify that this paper or, if this paper is a transmittal letter, every other paper or fee referred to therein, is being facsimile transferred to the Commissioner for Patents, at the United States Patent and Trademark Office, PO Box 1450, Alexandria, VA 22313-1450, on the date shown below

PLEASE CHARGE ANY DEFICIENCY UP TO \$300.00 OR CREDIT ANY EXCESS IN THE FEES DUE WITH THIS DOCUMENT TO OUR DEPOSIT ACCOUNT NO. 04-0100

September 8 2003 (Date of
Transmission)
9/8/03 Rat Campbell
Date Name
[Signature]
Signature

Customer No.:



07278

PATENT TRADEMARK OFFICE

Docket No.: 3940/OK188

DARBY & DARBY P.C.

Post Office Box 5257
New York, NY 10150-5257
212-527-7700

In re Application of: Michael Friedman; Mohammed S. Safadi

Serial No.: 09/534,960

Examiner: S. Lee Howard

Confirmation No.: 3862

Filed: March 27, 2000

Art Unit: 1615

For: CONTROLLED DELIVERY SYSTEM OF ANTIFUNGAL AND KERATOLYTIC
AGENTS FOR LOCAL TREATMENT OF FUNGAL INFECTIONS OF THE
NAIL AND SURROUNDING TISSUES

AMENDMENT TRANSMITTAL

Commissioner for Patents
PO Box 1450
Alexandria, VA 22313-1450

Sir:

Transmitted herewith is an amendment in the above-identified application. The fee has been calculated as shown below.

	Claims remaining after amendment	Highest number previously paid for	Present extra	Rate	Additional Fee
Total Claims	37	- 93 =	0	\$18	\$0.00
Independent	5	- 3 =	2	\$84	\$168.00
Multiple Dependent					\$

Total additional fee
for this amendment \$168.00

- ☐ Small Entity REDUCTION (Half of preceding total) \$.00
- ☐ No additional fee is required.
- ☐ A check in the amount of \$,00 is attached.
- ☒ Please charge any additional fees up to \$500.00 or credit overpayment to Deposit Account No. 04-0100. A duplicate copy of this sheet is enclosed.

Respectfully submitted,

Dated: September 8, 2003

Sandra Lee
Sandra S. Lee
Reg. No. 51,932
Attorney for Applicant(s)

DARBY & DARBY P.C.
Post Office Box 5257
New York, NY 10150-5257
212-527-7700

Serial No. 09/534,960
Amendment Transmittal

Docket No. 3940/OK188

-2-

M:\3940\Ok188\00053902.WPD [*39400K188*] /font=10

Received from < 212 753 6237 > at 9/8/03 9:08:56 PM [Eastern Daylight Time]

①